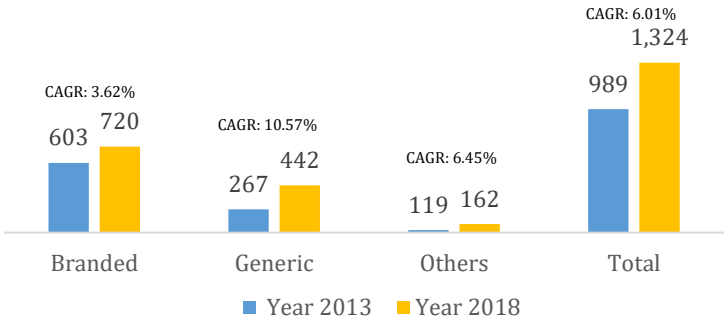
Generic Drugs: Revolutionary Change in the Global Pharmaceutical Industry

Over the last few years, generic drugs - low-cost copies of branded drugs - have been gaining in volume[i] and market share.[ii] Typically priced at significant discounts (50%-70%) to their branded counterparts, health plans and governments around the world, which are dealing with rapidly increasing costs and aging populations, have actively encouraged and promoted their use. Today in the US, generic drugs account for 88% of all prescriptions filled and according to latest IMS report, generics may account for 91%-92% of prescription volumes by 2020.

According to a report by IMS Health, from 2013-2018 generic drugs are expected to account for 52% of global pharmaceutical spending growth, compared to 35% for branded drugs. Overall, sales of generic drugs are forecast to increase from $267 billion in 2013 to $442 billion in 2017, an annualized growth rate of 10.6%. Major factors driving this growth include popular branded drugs losing their patent protection (known as a "patent cliff"), support for generics from governments, new complex generics coming into the market, and industry consolidation.

Figure 1: Global Pharmaceutical Sales ($ billion)



Source: IMS Health

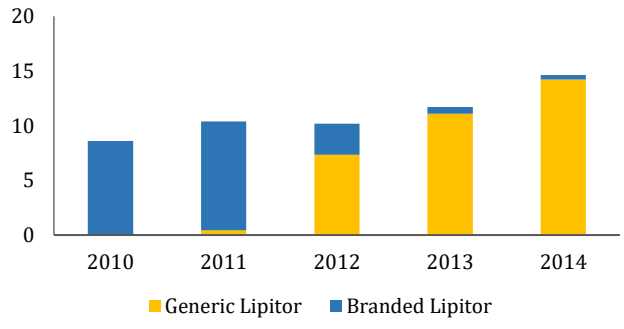
The Patent Cliff: $200 Billion in Branded Drugs Sales, Now Open to Generics

Traditionally, pharmaceutical companies develop new branded drugs by investing huge amounts of money (often more than $1 billion) into research and development over 10-15 years.[iii] This is the amount of time and money required to not only develop a number of potential new drugs, but go through the long, expensive and arduous approval process required by the US Food and Drug Administration (FDA) to prove a drug is safe and effective, and then market the drug to consumers. Since this model is so expensive and time consuming, the FDA typically gives drug companies 12 years of patent protection and a total monopoly on sales during that period. This allows the drugs companies to recoup their costs, earn a profit, and start the process anew for the next wave of new and innovative drugs.

In contrast, generic drug companies operate very differently. The amount of money they need to invest to produce a generic is many orders of magnitude less than the traditional branded drug companies, since the drug has already been formulated and approved. In order to protect the traditional branded drug companies and allow them to earn back the amount of money invested, generic drugs can only be introduced after the 12 years of patent protection has expired. And even then, FDA-approved copies of branded drugs are only given a short 180-day exclusivity period if their generic is the first to market. Once generic drugs are introduced to the market, they are typically sold at steep discounts (50%-70%) compared to the branded alternative and, as a result, branded drugs typically lose 90% or more of their market share to generics in a short amount of time.

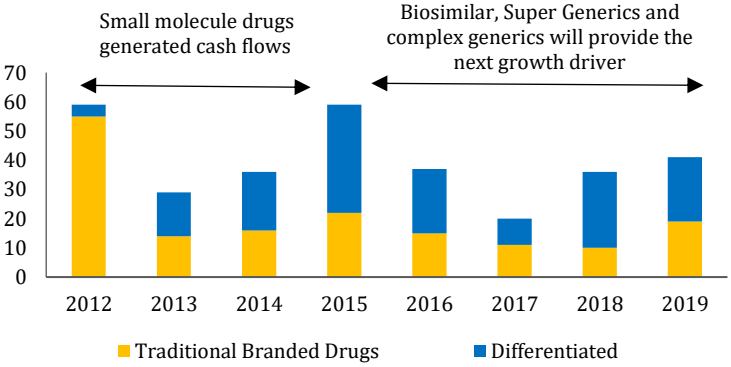
For example, Lipitor, an anti-cholesterol drug owned by Pfizer with annual sales of more than $10 billion, lost its patent protection in November 2011. Generic versions of the drug quickly entered the market and, by 2014, more than 97% of sales were from generic copies (Figure 2).

Figure 2: Annual Sales Lipitor ($ billion)



Source: Bloomberg Industries

Figure 3: Annual Sales of Drugs Losing Patent Protection ($ billion)



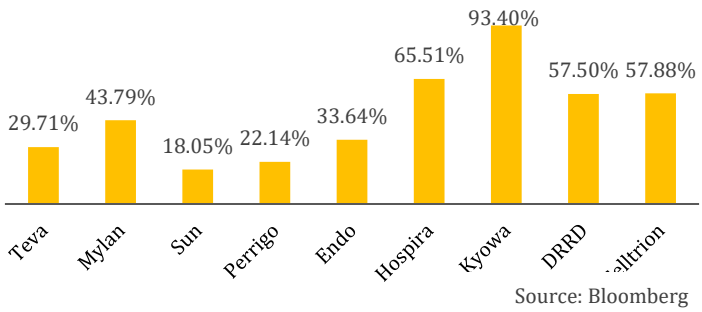
Source: Evaluate Pharma

The patent cliff is a trend that is expected to continue. From 2011-2020, drugs with annual sales of $200 billion will be losing their patent protection (Figure 3). This may lead not only to revenue losses for the traditional branded drug companies, but also the potential for significant new revenues for generic drug manufacturers. In fact, the patent cliff has generated enough financial resources and market clout for the generic manufacturers to help them transition from fringe players into what can be called the "New Big Pharma" industry, and move into new and exciting area and products.

Higher Complexity, Better Margins

Over the last few years, generic drug manufacturers have significantly increased their research & development spending as a percentage of their cash flows from operations (Figure 4). This is because they are starting to move into new, more complex products that will allow them to charge higher prices, boost their margins and protect themselves against the intense competition in the generic drug sector. Some of these new products are Biosimilars, Biobetters[iv] and SuperGenerics,[v] and will be powerful trends in the coming years.

Figure 4: Cumulative R&D to CFO (2011-2015)



Source: Bloomberg

Biosimilars are generic copies of a class of drugs called Biologics. However, Biologic drugs are much more complex than traditional branded drugs, not only in terms of their molecular structure but also in terms of their production (and are therefore much harder to copy). Biosimilars therefore require significantly more R&D investment and time to produce ($100 million-$200 million and 6 years) than typical generic drugs ($1 million-$5 million and 2 years).

In March 2014, Zarxio, a biosimilar to Amgen's Neupogen, was the first biosimilar approved in the US, opening a nearly $67 billion opportunity (the annual global sales of biologics losing patent protection between now through 2019) up to generic drug manufacturers. In Europe, the same biosimilar took 85% of the overall market share within four years of its launch. In the nearly 8 years following the introduction of the first biosimilar, only 4 biosimilars are in the market, with each having a market share of more than 15%. These high barriers to entry allow generic drug players to earn much higher margins and increase their profitability.[vi]

Accessing the Generic Drug & New Big Pharma Opportunity

Due to the growth of the space, generic drug manufacturers are a compelling investment theme for investors. There are also a number of other trends in the industry, from aging populations and higher healthcare spending to mergers and acquisitions that could make it even more attractive. These will be discussed by our research team in the coming weeks and months.

As a result of our extensive research into the space, Indxx has developed the Indxx Global Generics & New Pharma Index to provide access to the companies in this industry. The index includes exchange-listed companies, on a global basis, that derive a significant proportion of their revenues (or that have the potential to derive a significant proportion of their revenues) from the generic drug industry, or that have a primary business focus on the generic drug industry. The products of these companies are pharmaceuticals that are identical, or bioequivalent in the dosage form, safety, strength, quality and intended usage to brand name pharmaceuticals. As of December 31, 2015, the Index included 83 securities of companies with a minimum market capitalization of $1 billion and a weighted average market capitalization of $25.65 billion.

Indxx has licensed the index to noted New York-based asset manager and ETF sponsor Van Eck Associates Corporation for their exclusive use, and Van Eck has filed a notice to launch an ETF tracking the index under the symbol GNRX. The expected launch date is January 13, 2016.

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[i] http://www.pharmacytimes.com/publications/issue/2012/april2012/generic-drug-trends-whats-next-

[ii] http://www.cubex.co.in/PDF/Global_Pharmaceutical_Market.pdf

[iii] http://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/

[iv] Biobetters are new molecules that are related to already-approved biologics, but are deliberately altered to improve their disposition, safety, efficacy, or manufacturing attributes. They offer patent period protection and exclusivity period privileges similar to new biologics.

[v] SuperGenerics differ from the original drug in terms of formulation or method of delivery. They are generally better in their potency or effectiveness compared to original drug. SuperGenerics get 3 years of market exclusivity.

[vi] http://www.biorasi.com/wp-content/uploads/2015/03/bioRASI-Biosimilars-Presentation-04-12vw.pdf